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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,722	09/02/2005	Andrew Robert Davids	SER-102	6962

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EXAMINER

KIM, ALEXANDER D

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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11/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,722

Applicant(s)

DAVIDS ET AL.

Examiner

Alexander D. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63,66-70 and 73-78 is/are rejected.
- 7) ☒ Claim(s) 64,65,71 and 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (mailed on 06/15/2007), Applicants filed a response and amendment received on 09/17/2007. Said amendment cancelled Claims 1-62; amended Claims 63, 66-70 and 73-76.

Claims 63-78 are pending in the instant Office action. Thus, Claims 63-78 will be examined herein.

Oath/Declaration

2. The previous defective oath or declaration is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that disclosing the foreign priority in the ADS meets the requirements.

However, the MPEP 37 CFR 1.76 recites "Bibliographic data under 37 CFR 1.76(b) includes: (1) applicant information; (2) correspondence information; (3) application information; (4) representative information; (5) domestic priority information; (6) foreign priority information; and (7) assignee information. The naming of the inventors and the setting forth of the citizenship of each inventor must be provided in the oath or declaration under 37 CFR 1.63 (as is required by 35 U.S.C 115) even if this information is provided in the application data sheet." (emphasis added). Appropriate correction is required.

Withdrawn-Objections to the Specification

3. The previous objection of specification because the title is not descriptive of the claims is withdrawn by virtue of Applicants' amendment.

Maintained-Objections to the Specification

4. The previous objection of specification because the Abstract does not completely describe the disclosed subject matter (see M.P.E.P. § 608.01(b)) is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue the instant Abstract has been amended. However, the amendment is insufficient.

Withdrawn-Compliance with Sequence Rules

5. The previous non-compliance with sequence rules is withdrawn by virtue of Applicants' amendment of the description of the Figures.

Claim Objections

6. Claims 64,65,71 and 72 are objected to because they depend from rejected claims.
7. Claims recite the wrong Serial number (i.e., 10/526,772). It should be --- 10/526,722---. Appropriate correction is required.

Withdrawn-Claim Rejections - 35 USC § 112

8. The previous rejection of Claims 63-78 under of 35 U.S.C. 112, second paragraph, is withdrawn by virtue of Applicants' amendment.

Maintained-Claim Rejections - 35 USC § 112

9. The previous rejection of Claims 63, 66-70, 73-78 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that there is adequate written description for the claimed subject in the specification and in view of deleting the phrase "over its full length to the amino acid sequence" and amending instant claims to have limitation of "kinase activity or activates the MAP kinase pathway.

However, the instant amendments do not overcome the instant rejections because instant claims still encompasses any isolated polypeptide comprising any amino acid sequence that has a certain % identity to any portion of the amino acid sequence within SEQ ID NO: 100, or comprising any fragment of SEQ ID NO: 100, as small as two consecutive amino acids; wherein said isolated polypeptide has kinase activity or activates the MAP kinase pathway. Claims 66-69 and 73-76 have been interpreted to have same scope except more stringent % identity; thus, containing any fragment of SEQ ID NO: 100. Furthermore, the instant specification and prior art do not adequately describe the claimed polypeptide sufficiently to represent the correlation

between the structure and function of claimed genus that is a polypeptide with any kinase activity or having any property of activating the MAP kinase pathway in any organism. For the reasons above, instant rejection is maintained.

10. The previous rejection of Claims 63, 66-70, 73-78 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue claims are enabled by the subject in the specification and in view of deleting the phrase "over its full length to the amino acid sequence" and amending instant claims to have limitation of "kinase activity or activates the MAP kinase pathway.

However, as noted above, the instant amendments do not overcome the instant scope of enablement rejection because instant claims still encompasses any isolated polypeptide of Claims 63 and 70 comprise any amino acid sequence that has a certain % identity to any portion of the amino acid sequence within SEQ ID NO: 100, or comprising any fragment of SEQ ID NO: 100, as small as two consecutive amino acid; wherein said isolated polypeptide has kinase activity or activates the MAP kinase pathway. The Claims 66-69 and 73-76 have been interpreted to have same scope of limitation except more stringent % identity; thus, containing any fragment of SEQ ID NO: 100. As previously disclosed, the applicants disclose no direction or guidance on how to make and use any other isolated polypeptide encompassed by the instant claims; thus the specification and prior art fail to describe how to make and use the claimed

genus sufficiently. Therefore, it is unpredictable for any polypeptide comprising any portion within the SEQ ID NO: 100 having any kinase activity or having any property of activating the MAP kinase pathway in any organism. Thus, the level of skill is high by the instant genus claims for one skilled in the art to make and use the full scope of claims. For all of the above reasons, it would require undue experimentation necessary for a claimed genus polypeptide described above. Thus, the instant rejection is maintained.

Withdrawn-Claim Rejections - 35 USC § 101

11. The previous rejection of Claims 63-78 under 35 U.S.C. §101 because the claimed invention lacks patentable utility is withdrawn by virtue of Applicants' amendment and in view of Applicants' argument providing the usefulness of the MAP kinase pathway.

Withdrawn-Claim Rejections - 35 USC § 102

12. The previous rejection of Claims 64-65 and 71-72 rejected under 35 U.S.C. 102(b) as being anticipated by Nakano et al. (2000, The Journal of Biological Chemistry, vol. 275, page 20533-20539, as cited in IDS) is withdrawn based upon the Applicants' argument.

Maintained-Claim Rejections - 35 USC § 102

13. The previous rejection of Claims 63, 66-70, 73-78 under 35 U.S.C. 102(b) as being anticipated by Nakano et al. (2000, The Journal of Biological Chemistry, vol. 275, page 20533-20539, as cited in IDS) is maintained.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue the Nakano et al. reference does not anticipate the claimed invention as it fails to teach a polypeptide that has at least 95% identity to SEQ ID NO: 100.

However, because the instant claims encompass a broad polypeptide comprising any amino acid sequence that is 95, 96, 97, 98 or 99 % identity to any portion of the amino acid sequence within SEQ ID NO: 100, or comprising any fragment of SEQ ID NO: 100, as small as two consecutive amino acid; wherein said isolated polypeptide having a kinase activity; the Nakano et al. teach a polypeptide encompassed by the instant claims. As disclosed in the previous office action, the Nakano et al. teach a polypeptide NESK, a member of germinal kinase, comprising an amino acid sequence wherein said sequence of its full length has 100% identical to a corresponding sequence of SEQ ID NO: 100 as shown in the SEQ Alignment in the attachment. The polypeptide of Nakano et al. comprising the MAGP (very first 4 consecutive amino acid sequence) wherein the full length of MAGP is 100% identical to the corresponding amino acid sequence of SEQ ID NO: 100. The protein NESK of Nakano et al. was isolated as evidenced by the cell lysed with "400 ul of lysis buffer" and centrifuged as

disclosed in Experimental Procedures, top of right column, page 20534. The water used to make the lysis buffer by Nakano et al. meets the limitation of pharmaceutical carrier and as an adjuvant. Thus, the polypeptide of Nakano et al. meets the limitation of Claims 63, 66-70, 73-78.

Additional Notes

14. Claims 64-65 and 71-72 have been interpreted as a polypeptide having the full length of SEQ ID NO: 100 and do not encompass any fragment thereof.

Conclusion

15. Claims 63, 66-70, 73-78 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

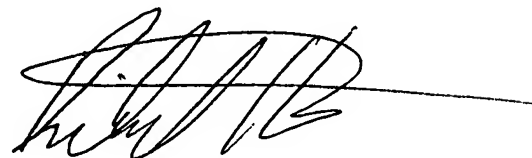
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alexander Kim

November 13, 2007

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal line extending to the right.

**RICHARD HUTSON, PH.D.
PRIMARY EXAMINER**